Contact lens disinfectants monograph

1.Description

This monograph applies to products in liquid or tablet form intended to be used to disinfect contact lenses. It does not apply to contact lens disinfectants that contain mercury or a salt or derivative thereof (Section C.01.036 of the *Food and Drug Regulations*).

2.Pharmaceutical quality

1.All ingredient (medicinal and nonmedicinal) and finished product specifications should as a minimum meet Schedule B or equivalent standards. Where no schedule B monograph exists for the dosage form, specifications should be similar to those of a comparable compendial dosage form. In the absence of a Schedule B standard for any dosage form, testing should be adequate to demonstrate the product's identity, potency, purity and quality.

2.Special notes: Manufacturers should meet as a minimum the requirements of Section XIII, Ophthalmic Preparations, of the Therapeutic Products Directorate Guidelines, Preparation of Drug Identification Number Submissions, February 1995, with the exception of the requirements of Section XIII-B Conditions.

3.Ingredients

The medicinal, i.e., active ingredients, their concentrations and their combinations in Monograph products are restricted to those specified in this monograph.

a. Single medicinal ingredients

The medicinal, i.e., active ingredients should be identified on product labelling by the names given in Table 1; both preferred names and synonyms are considered acceptable. This Table also indicates the acceptable concentrations corresponding to each active ingredient represented in a contact lens disinfectant.

Table 1 Single medicinal ingredients

Preferred name	Synonym	Acceptable concentration
Alkyltriethanolammonium chloride	Quaternium-16	≥ 0.03%
Benzalkonium chloride	Alkyl dimethyl benzyl ammonium chloride	≥ 0.01%
Chlorhexidine gluconate	Chlorhexidine digluconate	≥ 0.0035%
Hydrogen peroxide	Hydrogen dioxide	≥ 3%
Isopropyl alcohol	Isopropanol	≥ 15%

Polyaminopropyl biguanide		≥ 0.00005%
Polyquaternium-1	Polyquad	≥ 0.001%
Polyhexanide		≥ 0.0001%
Tris (2-hydroxyethyl) tallow ammonium chloride		≥ 0.013%

b. **Combinations of medicinal ingredients**

The following combinations are considered acceptable. The lower limits for use as a single ingredient also apply when the ingredient is used in combination.
1.Chlorhexidine and EDTA
2.Alkyltriethanolammonium chloride and EDTA
3.Chlorhexidine, Polyaminopropyl biguanide and EDTA
4.Polyquaternium-1 and EDTA

c. **Special notes**

EDTA may be considered to represent a medicinal ingredient if the manufacturer has data available which show that it is essential for the efficacy of the product. EDTA enhances the activity of a number of medicinal ingredients (e.g., chlorhexidine, benzalkonium chloride, polyquaternium-1, alkyltriethanolammonium chloride) by chelating calcium and magnesium ions.

d. **Nonmedicinal ingredients**

Nonmedicinal ingredients should be restricted to the substances that are necessary for the formulation of the particular dosage form. Their concentration should not exceed the minimum required to provide their intended effect. They should be harmless in the amounts used, their presence should not adversely affect the efficacy or safety of the medicinal ingredients, and they should not interfere with tests for the medicinal ingredients or, if present, antimicrobial preservatives.

e.Labelling

1.This monograph describes the requirements that are specific to this class of drugs. Other requirements described in the *Food and Drugs Act* and *Regulations* should also be met.

2.Directions for Use
a.Indications - all products should indicate:
- disinfectant (or antimicrobial solution), and
- use on a specific type(s) of contact lenses, eg., hard, soft (hydrophilic, tinted, etc.).

b.Directions for Use:
- wash and dry hands thoroughly before handling the lenses;

- preclean the lenses prior to disinfection. (Unless the labelling clearly indicates that the disinfectant or antimicrobial solution is intended to clean the lenses in addition to disinfecting and the directions for use reflect this additional function);
- contact or soaking time required to disinfect the lenses;
- neutralising step, if appropriate (for example, use catalase for products containing hydrogen peroxide);
- rinse procedure after disinfection.

3.Warnings

- If irritation develops with the use of this product, discontinue use and consult your eye care practitioner;
- Do not touch tip of the bottle to any surface since this may contribute to contamination of the solution;
- Always keep the bottle tightly closed;
- Always use fresh solution and discard after use. Do not reuse solution.